

K121982

**SOVEREIGN® Spinal System
510(k) Summary
July 5, 2012**

JUL 26 2012

- I. Company:** Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, TN 38132
Telephone: (901) 396-3133
FAX: (901) 346-9738
- II. Contact:** Lauren Kamer
Senior Regulatory Affairs Specialist
- III. Proprietary Trade Name:** SOVEREIGN® Spinal System
- IV. Common Name:** Intervertebral Fusion Device with Integrated Fixation, Lumbar
- V. Classification Name:** Intervertebral Body Fusion Device (21 CFR 888.3080)
Class: II
Product Code: OVD

VI. Product Description

The SOVEREIGN® Spinal System is an intervertebral body fusion device with integrated screw fixation. The screws protrude through the interbody portion of the device and stabilize the vertebral body while preventing expulsion of the implant. The implant is lens-shaped with three holes for placement of titanium screws. The SOVEREIGN® Spinal System contains both a fixed and a variable angle screw option. The fixed angle screw option provides an interference fit with the PEEK interbody implant. The variable angle screw option provides a slight clearance between the PEEK interbody implant and the screw which allows for a small amount of variable screw angulation. This system is intended to be radiolucent and the interior space of the product is to be used with autogenous bone graft. The accompanying cover plate is designed to resist screw backout and must be used when the variable angle screws are implanted. The SOVEREIGN® Spinal System interbody device is manufactured from PEEK (polyetheretherketone) and contains tantalum radiopaque markers. The screws used with this device are manufactured from titanium alloy.

The SOVEREIGN® Spinal System includes instrumentation that enables the surgeon to implant the devices via a laparoscopic or an open anterior approach. The purpose of this Special 510(k) submission is to make modifications to the inserter sleeve that is part of SOVEREIGN® Spinal System. The inserter sleeve is a cylindrical stainless steel sleeve, incorporating a polymer bushing, which is used in conjunction with the inserter knob and one of three inserter shafts to securely hold a SOVEREIGN® interbody implant during insertion and impaction into the vertebral disc space.

VII. Indications for Use

The SOVEREIGN® Spinal System is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via a laparoscopic or an open anterior approach.

The SOVEREIGN® interbody system may be used as a stand-alone device or in conjunction with supplemental fixation.

When used as a stand-alone device, the SOVEREIGN® interbody device is intended to be used with the three titanium alloy fixed or variable angle screws. The accompanying cover plate **MUST** be used anytime the device is used with any number of variable angle screws. If the physician chooses to use less than three or none of the provided screws, then additional supplemental fixation for use in the lumbar spine must be used to augment stability.

VIII. Summary of Technological Characteristics

The fundamental scientific technology of the subject SOVEREIGN® Spinal System is identical to the predicate SOVEREIGN® Spinal System.

Both the subject SOVEREIGN® Spinal System and predicate SOVEREIGN® Spinal System implants are lens-shaped interbody devices with integrated screw fixation, designed to contain autograft material and to facilitate fusion between two vertebral bodies. Both subject and predicate interbody devices are made from PEEK, possess tantalum markers for x-ray visualization, and are used with titanium alloy screws.

Both the subject SOVEREIGN® Spinal System and the predicate SOVEREIGN® Spinal System include instrumentation that enables the surgeon to implant the devices via a laparoscopic or an open anterior approach. The inserter sleeve used with both the subject and predicate SOVEREIGN® Spinal System is a cylindrical stainless steel sleeve, incorporating a polymer bushing, which is used in conjunction with the inserter knob and one of three inserter shafts to securely hold the interbody implant during insertion and impaction into the vertebral disc space. Both the subject and predicate inserter sleeves are constructed from materials with a history of safe and effective use in orthopedic surgical instruments. The subject inserter sleeve is made from stainless steel with a Radel polyphenylsulfone bushing; the predicate inserter sleeve is made from stainless steel with a Delrin polyoxymethylene bushing.

IX. Identification of the Legally Marketed Predicate Device Used to Claim Substantial Equivalence

In order to demonstrate substantial equivalence to legally marketed predicate devices, SOVEREIGN® Spinal System (K091813, SE Nov 17, 2009, and K110063, SE Oct 4, 2011) is used as the primary predicate for intended use and fundamental scientific technology. The following additional predicates are being used to support the instrument sterilization and cleaning rationale included in this submission:

- CAPSTONE CONTROL™ Spinal System (K120368, SE April 9, 2012),
- PERIMETER® Interbody Fusion Device (K113642, SE Feb 6, 2012), and
- TELAMON® PEEK Spinal System (K110562, SE Nov 9, 2011).

X. Brief Discussion of the Non-Clinical Tests Submitted

Assessment of the instrument modifications has been completed in accordance with Medtronic design control processes. Mechanical (axial pull) testing and other verification/validation activities, including tolerance analyses and user validation, were conducted to confirm that the modified instrument functions as intended and does not raise any new issues of safety or effectiveness.

A cleaning and sterilization assessment has been conducted to provide the appropriate disassembly, cleaning, and sterilization instructions for the modified inserter sleeve, as well as the other instruments for use with SOVEREIGN® Spinal System. The referenced cleaning and sterilization validations were conducted in accordance with the following standards:

- ISO 17664:2004 , Sterilization of medical devices- Information to be provided by the manufacturer for the processing of resterilizable medical devices
- ANSI/AAMI/ISO 17665-1:2006 , Sterilization of health care products- Moist heat- Part 1: Requirements for development, validation, and routine control of sterilization process for medical devices
- ANSI/AAMI/ISO TIR 17665-2:2009 , Sterilization of health care products- Moist heat- Part 2: Guidance on the application of ANSI/AAMI/ISO 17665-1
- AAMI TIR 12:2010 , Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for device manufacturers
- ANSI/AAMI ST79:2010 & A1:2010 , Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- AAMI TIR 30:2003 , A compendium of processes, materials, test methods and acceptance criteria for cleaning reusable medical devices
- ANSI/AAMI ST81:2004 , Sterilization of medical devices - Information to be provided by the manufacturer for the processing of re-sterilizable medical devices

XI. Conclusions Drawn from the Non-Clinical Tests

The subject and predicate SOVEREIGN® Spinal System are identical in terms of indications for use, intended use, performance specifications, and fundamental technological characteristics. A risk analysis and associated verification/validation testing was completed for the instrument modifications. Based on the risk analysis and additional supporting documentation provided in this premarket notification, Medtronic believes the subject SOVEREIGN® Spinal System to be substantially equivalent to legally marketed predicate devices, including the previously cleared SOVEREIGN® Spinal System (K091813, SE Nov 17, 2009, and K110063, SE Oct 4, 2011).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

JUL 26 2012

Medtronic Sofamor Danek
% Ms. Lauren Kamer
Senior Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K121982

Trade/Device Name: SOVEREIGN Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: July 05, 2012
Received: July 06, 2012

Dear Ms. Kamer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

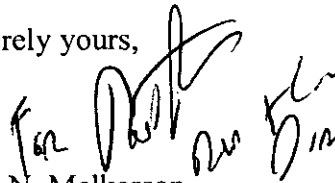
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CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", is written over the typed name.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K121982

510(k) Number (if known): K121982

Device Name: SOVEREIGN® Spinal System

Indications for Use:

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121982